68-7-21. Institutional Drug Rooms. (a) Institutional drug rooms shall only dispense drugs that are approved by the U.S. Food and Drug Administration. Except for drugs that are in liquid or cream forms, all drugs dispensed for administration to humans shall be in prepackaged units. The prepackaging shall comply with the requirements of K.A.R. 68-7-15.

(b) Each pharmacist or practitioner, as that term is defined in K.S.A. 65-1637a, responsible for supervising the institutional drug room shall perform the following:

(1) Develop or approve programs for training and supervision of all personnel in the dispensing and control of drugs;

(2) develop or approve a written manual of policies and procedures governing the storage, control, and dispensing of drugs when a pharmacist or practitioner is not on duty;

(3) maintain documentation of at least quarterly reviews of drug records, drug storage conditions, and drugs stored in all locations within the institutional drug room;

(4) develop or approve written procedures for maintaining records of the dispensing and prepackaging of drugs; and

(5) develop or approve an incident reporting system that complies with the requirements of K.A.R. 68-7-12b.

(c) The procedures for the control and dispensing of drugs in the institutional drug room shall comply with the following requirements:

(1) A record of all drugs dispensed in the institutional drug room shall be maintained in the patient's file and shall include the practitioner's order or written protocol.

(2) If the practitioner's order was given orally, electronically, or by telephone, the order shall be recorded, either manually or electronically. The recorded copy of the order shall include

the name of the person who created it and shall be maintained as part of the permanent patient file.

(3) The records maintained in the patient's file shall include the following:

(A) The full name of the patient;

(B) the date the drug was dispensed;

(C) the name of the drug, the quantity dispensed, and strength of the drug dispensed;

(D) the directions for use of the drug; and

(E) the prescriber's name, and , if the prescriber is a practitioner's assistant or advanced registered nurse, the name of that person's supervising practitioner.

(d) All drugs dispensed in an institutional drug room shall be in a container or package that contains a label that contains the following information:

(1) The name, address, and telephone number of the institutional drug room from which the drug is dispensed;

(2) the name of the person dispensing the drug;

(3) the full name of the patient;

(4) adequate directions for use of the drug;

(5) the prescriber's name, and , if the prescriber is a practitioner's assistant or advanced registered nurse, the name of that person's supervising practitioner.

(6) the date the drug was dispensed;

(7) the identification number assigned by the institutional drug room to the drug dispensed;

(8) the brand name or corresponding generic name of the drug;

(9) any necessary auxiliary labels and storage instructions; and

(10) the beyond-use date of the drug dispensed.

(e) All labels for prepackaged drugs shall also contain the following information:

(1) the name of the manufacturer or distributor of the drug or an easily identified abbreviation of the manufacturer or distributor's name;

(2) the strength of the drug;

(3) the contents of the prepackaged units in terms of weight, measure, or numerical count.

(Authorized by and implementing K.S.A. 65-1637a; effective P- _____.)